Amendments to the Claims

This listing of claims replaces all prior versions, and listings, of claims in the application:

1. (currently amended) An assay device for measuring serum cholesterol associated with high-density lipoproteins (HDL) in a blood fluid sample containing lipoproteins other than HDLs of the type including a sample distribution array effective to distribute a blood fluid sample from a sample application region to one or more sample collection regions, the device comprising:

~~a sample distribution array;~~

a HDL test pad in which HDL concentration can be assayed being spaced apart from said array, said HDL test pad being affixed to a mounting means; and

a reagent pad containing a binding reagent effective to selectively bind and remove non-HDLs from the fluid sample;

wherein said HDL test pad and said reagent pad are joined;

wherein said mounting means are effective (i) to maintain the device in a sample-distribution position, wherein said joined HDL test pad and reagent pad are spaced apart from said array, and (ii) to transfer said device to a test position, whereby the joined HDL test pad and reagent pad are in contact with said array.

2. (original) The device of claim 1, wherein said HDL test pad and said reagent pad are joined by a heat formed bond.

3. (original) The device of claim 1, wherein said HDL test pad and said reagent pad are joined by an acrylic acid copolymer adhesive bond.

4. (original) The device of claim 3, wherein said acrylic acid copolymer is ethylene acrylic acid copolymer.

5. (original) The device of claim 1, wherein at least one of said HDL test pad or said reagent pad is composed of a polysulfone layer.

6. (currently amended) The device of claim 1, further comprising a sieving pad in fluid communication with said sample application region and said one or more sample collection regions effective to remove cellular components from the blood fluid sample prior to the sample contacting said sample distribution array.

7. (currently amended) The device of claim ~~1~~6, further comprising a cassette body for containing said sieving pad, said cassette body comprising a well for containing said blood fluid sample and in fluid communication with said sieving pad.

8. (original) The device of claim 7, further comprising a reaction bar comprising mounting means effective to attach said reaction bar to said cassette body.

9. (original) The device of claim 1, wherein said reagent comprises a binding polyanionic reagent.

10. (original) The device of claim 9, wherein said binding polyanionic reagent includes a sulfonated polysaccharide.

11. (original) The device of claim 1, wherein said HDL test pad contains reagents which produce a detectable change in the presence of HDL cholesterol.

12. (original) The device of claim 11, wherein said change can be detected optically.

13. (original) The device of claim 1, wherein said HDL test pad comprises a biosensor.

14. (original) The device of claim 13, wherein said biosensor is effective to electrochemically measure production of oxygen or hydrogen peroxide.

15. (currently amended) A method of preparing a device suitable for measuring serum cholesterol comprising:

providing a reagent pad and an HDL test pad, wherein at least the reagent pad is formed of an asymmetric polysulfone membrane having a small pore side and an open pore side;

~~orienting the reagent pad with the HDL test pad such that the small pore side of the reagent pad contacts the open pore side of the HDL test pad;~~

heating to adhere said HDL test pad and said reagent pad; and

applying (i) HDL test reagents to said HDL test pad, and (ii) a reagent effective to selectively bind and remove non-HDLs from a fluid sample to said reagent pad to form said device.

16. (original) The method of claim 15, wherein said heating is at a temperature above 165° C.

17. (currently amended) A method of preparing a device suitable for measuring serum cholesterol comprising:

coating a reagent pad with an acrylic acid copolymer;

applying (i) HDL test reagents to ~~said~~an HDL test pad, and (ii) a reagent effective to selectively bind and remove non-HDLs from a fluid sample to said reagent pad;

heating to adhere said HDL test pad and said reagent pad to form said device.

18. (original) The method of claim 17, wherein said acrylic acid copolymer is ethylene acrylic acid copolymer.

19. (original) The method of claim 18, wherein the ethylene acrylic acid copolymer is about 4.0% to about 10.0% emulsion.

20. (original) The method of claim 17, further comprising the step of drying said reagent pad after said coating step.

21. (original) The method of claim 17, wherein each of said HDL test pad and reagent pad have a small pore side and an open pore side; further comprising the step of orienting the HDL test pad and the reagent pad such that the small pore side of the reagent pad faces the open pore side of the HDL test pad.

22. (original) The method of claim 17, wherein said heating step comprises applying a temperature of between 75° and 90° C.

23. (currently amended) A method of measuring serum cholesterol associated with high-density lipoproteins (HDL) in a blood fluid sample containing lipoproteins other than HDLs, comprising:

contacting a sample reservoir containing the sample with a laminate comprising (i) an HDL test pad having a detectable indicator of HDL cholesterol, (ii) a reagent pad containing a reagent effective to selectively bind and remove non-HDLs from the fluid sample;

wherein said blood fluid sample passes through said laminate by capillary action and/or gravity through said laminate to permit measurement of HDL concentration.

24. (currently amended) The method of claim 23, wherein contact between said ~~sieving pad~~laminate and said sample reservoir~~distribution pad~~ is broken when a desired amount of sample has been transferred.

25. (original) The method of claim 23, wherein said reagent comprises a sulfonated polysaccharide.

26. (original) The method of claim 23, wherein at least one of said HDL test pad or said reagent pad comprises a porous polymeric membrane.

27. (original) The method of claim 23, wherein said reagent pad comprises multiple stacked layers, at least one of which contains a reagent effective to bind non-HDLs.

28. (original) The method of claim 23, wherein said measurement of HDL concentration is via optical detection.

29. (original) The method of claim 23, wherein said HDL test pad comprises a biosensor.

30. (original) The method of claim 29, wherein said biosensor is effective to electrochemically measure production of oxygen or hydrogen peroxide.

31. (new) The method of claim 15, wherein each of said HDL test pad and said reagent pad are formed of an asymmetric polysulfone membrane having a small pore side and an open pore side, said method further comprising:

before said heating, orienting the reagent pad with the HDL test pad such that the small pore side of the reagent pad contacts the open pore side of the HDL test pad.